

## PHARMACY BOARD [657]

### Notice of Intended Action

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 22, “Unit Dose, Alternative Packaging, and Emergency Boxes,” Iowa Administrative Code.

The amendments were approved at the August 28, 2013, regular meeting of the Board of Pharmacy.

The proposed amendments provide that a medication strip pack prepared for a patient utilizing an automated dispensing system is not a unit dose package. Such a strip pack is a patient med pak and is subject to the requirements regarding patient med paks. The proposed amendments also prohibit the return to pharmacy stock or the automated dispensing system of a drug dispensed in a strip pack or other patient med pak unless the drug was dispensed as a single unit and was not comingled with other patient medications in a single package or container.

Requests for waiver or variance of the discretionary provisions of Board rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on October 22, 2013. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to [terry.witkowski@iowa.gov](mailto:terry.witkowski@iowa.gov).

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 126.9, 126.10, 126.11, 155A.13, 155A.28, 155A.35, and 155A.36.

The following amendments are proposed.

Item 1. Amend 657 subrule 22.1(1), definition of “Unit dose package,” as follows:

“*Unit dose package*” means a package that contains that particular dose of a drug order for the patient for one administration time. A unit dose package is not always a single unit package. *Unit dose package*” does not include a strip pack prepared utilizing an automated dispensing system. A strip pack is a patient med pak subject to the requirements of rule 657—22.5(126,155A).

Item 2. Amend 657 subrule 22.5(1) as follows:

**22.5(1) Definition.** A patient med pak is a customized patient medication package prepared for a specific patient which comprises a series of immediate containers containing prescribed solid oral dosage forms, each container being labeled with the time or the appropriate period for the patient to take its contents. A patient med pak includes but is not limited to a strip pack prepared utilizing an automated dispensing system.

Item 3. Amend 657 subrule 22.5(4) as follows:

**22.5(4) Repackaging of patient med paks.** In the event a drug is added to or discontinued from a patient’s drug regimen, the pharmacist may repack the patient’s med pak and either add to or remove from the patient’s drugs packaged as ordered by the prescriber. Drugs returned by the patient for repackaging ~~shall~~ may be reused by the pharmacist in the design of the new patient med pak, and any drug removed from the new drug regimen shall either be disposed of in compliance with board rules or returned, properly labeled, to the patient. Under no circumstances shall a drug within a container of a patient med pak be returned to the pharmacy stock or returned to an automated dispensing system component unless the drug was dispensed as a single dose and was not comingled with other patient medications in a single package or container.